

Attorney Docket No.: 1340-1-034N (SJ-0029)
Inventors: Schuetz et al.
Serial No.: 09/974,619
Filing Date: October 10, 2001
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The claims of the present application have been subjected to a Restriction Requirement under 35 U.S.C. §121 and 37 C.F.R. §1.141 by the Examiner in this case as follows:

Group I, claims 1-32 drawn to methods of genotyping and methods of predicting levels of gene expression, classifiable in class 435, subclass 6;

Group II, claim 33-34 and 37, drawn to kits and primers for detecting a CYP3A5 gene polymorphism at nucleotide 22,893 classifiable in class 536, subclass 24.33; and

Group III, claims 35-36 and 38, drawn to kits and primers for detecting a CYP3A5 gene polymorphism at nucleotide 30,597, classifiable in class 536, subclass 24.33.

The Examiner suggests that the inventions are distinct each from the other because they are related as product and process of use. It is suggested that the products of Groups II and III may be used in materially different processes, such as methods of nucleic acid sequencing, or methods of detecting homologues of the CYP3A5 gene. Groups II and III are suggested to be patentably distinct products. It is suggested that while Groups II and III are each products that include oligonucleotides that amplify portions of the CYP3A5 gene, the oligonucleotides of Groups II and III have different sequences and therefore different structures. It is

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further suggested that the two Groups would have different functional properties as a polymorphism detected by Group II would not be an obvious variant of a polymorphism detected by Group III. It is further suggested that Groups I-III require different text and sequence searches that are not co-extensive and inclusion of all three Groups would pose a serious burden on the Examiner.

Applicants respectfully traverse this restriction requirement.

MPEP §803 is quite clear; for a proper restriction requirement, it must be shown (1) that the inventions are independent or distinct AND (2) that there would be a serious burden on the Examiner if the restriction is not required. MPEP 802.01 defines "distinct" to mean that the "two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made there, etc., but are capable of separate manufacture, use, or sale, as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER."

As acknowledged by the Examiner, all of the claims are related to a common gene, namely CYP3A5 and methods and materials for genotyping and predicting expression of this gene. Thus, Applicants respectfully disagree with the Examiner's suggestion

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that designated groups are distinct as being novel and unobvious over each other as required by MPEP § 802.01. Further, a search relating to CYP3A5 would identify art relevant to all three groups because any such search will necessarily focus on the CYP3A5 gene sequence and variants thereof. Thus, no serious burden would be presented to the office if all three groups are examined together. Accordingly, reconsideration and withdrawal restriction requirement is respectfully requested.

However, in an earnest effort to be completely responsive, Applicants hereby elect to prosecute Group I, claims 1-32 with, traverse.

Respectfully submitted,



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